Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554

In the Matter of	)	
	)	
Amendment of Parts 2 and 95 of the	)	RM-11271
Commission's Rules to Establish the	)	
Medical Device Radio Communications	)	
Service at 401-402 and 405-406 MHz	)	

COMMENTS OF BOSTON SCIENTIFIC CORPORATION CARDIAC RHYTHM MANAGEMENT

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The Cardiac Rhythm Management business unit of Boston Scientific Corporation[1] (formerly Guidant Corporation) ("BSCCRM"), by its attorneys, respectfully submits its comments in the above-captioned proceeding. These comments respond to the Notice of Proposed Rulemaking ("NPRM") and the Notice of Inquiry ("NOI") released by the Commission on July 18, 2006.[2]

BSCCRM is a leading worldwide manufacturer of medical devices for cardiac patients and has been manufacturing implantable devices with "communications features" since the early 1970s. BSCCRM heart devices include: implantable pacemakers, cardioverter defibrillators ("ICDs")[3] and cardiac resynchronization therapy ("CRT") devices;[4] and external clinical and home monitoring equipment associated with

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[1] BSCCRM is a division within Boston Scientific Corporation that develops implantable devices to detect and treat abnormalities in the heart's rhythm and function, including cardiac arrhythmias, sudden cardiac arrest and heart failure.

[2] *In the Matter of Amendment of Parts 2 and 95 of the Commission's Rules to Establish The Medical Data Service at 401-402 and 405-406 MHz*, RM-11271, Notice of Proposed Rulemaking, Notice of Inquiry and Order (released July 18, 2006).

[3] Carioverter defibrillators treat heart rhythms that are abnormally fast, a condition called tachyarrhythmia. An ICD is able to monitor the heart's activity and respond with an electrical shock when an arrhythmia occurs. The memory in the device stores information on the heart's function before, during and after an arrhythmia, as well as the heart's response to the electrical shock. After implant, a physician can check and adjust an ICD's functions by using an external device called a programmer/recorder/monitor ("PRM"). The PRM communicates with the ICD by RF transmissions or from an inductive telemetry wand held over the implant site.

[4] CRT devices deliver electrical impulses to the heart to resynchronize heart rhythms in heart failure patients.

these implantable devices. Thus, BSCCRM will be directly affected by the outcome of this proceeding and has a stake in any rules that may be adopted.

BSCCRM commends the Commission for initiating this proceeding to expand the spectrum allocated to the Medical Implant Communications Service ("MICS") and to request comment on the evolution of implantable medical devices and the need to revise the operating rules for MICS. However, BSCCRM cautions the Commission against taking an overly narrow approach that may preclude much-needed MICS reform as proposed herein and which BSCCRM urges the Commission to consider in its NOI. In this respect, BSCCRM is most concerned about the Commission making any changes to MICS that might limit the flexibility of this service to accommodate emerging medical technologies and new uses of implantable medical telemetry.

Summary

In its NPRM, at the request of Medtronic, Inc. ("Medtronic"), the Commission proposes to add 2 MHz of spectrum on either side of the existing MICS allocation at 401-402 MHz and 405-406 MHz ("Wing Bands"), for body-worn and implanted radio transmitting devices which would operate in a new service combined with MICS called the Medical Device Radiocommunication Service ("MedRadio").[5] Devices operating at higher power would be required to employ frequency-monitoring technology as devices operating in the MICS band are required currently. Devices that operate with very low power and low duty cycles (250 nanowatts and a 0.1% duty cycle) would be permitted to operate without frequency monitoring.[6]

BSCCRM disagrees with the Medtronic approach and, instead, agrees with the comments of Biotronik, Inc.[7] and DexCom[8] that a two-tiered structure for an expanded MICS band to accommodate body-worn devices is unnecessary and ill-advised. Other technologies such as Bluetooth, 802.11x and ultra wideband can be used for external or body-worn medical device communications, whereas the MICS band is uniquely

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[5] NPRM at ¶ 20.
[6] *Id.* at ¶¶ 15, 23 and 25.
[7] *In the Matter of Amendment of Parts 2 and 95 of the Commission's Rules to Establish The Medical Data Service at 401-402 and 405-406 MHz,* RM-11271, Comments of Biotronik, Inc. (October 11, 2005).

allocated and designed for implant telemetry. BSCCRM submits that the more prudent course of action is to modify the current MICS rules to accommodate a broader range of implantable medical devices, including those that operate inductively below 1 MHz. BSCCRM is concerned that devices in the Wing Bands, with different technical standards than MICS, will impede the Commission's ability to add much-needed spectrum for implants and limit the ability of MICS to accommodate future technologies such as implantable drug delivery systems, devices that electrically stimulate body functions, and implantable diagnostic devices. BSCCRM recommends instead that the Commission expand the spectrum for implantable devices by adding the 401-402 MHz and 405-416 MHz bands to the current MICS allocation.

The NPRM also requests comment on the proposal of Medtronic to limit the maximum channel bandwidth in the proposed additional 2 MHz to 100 kHz.[9] BSCCRM believes that the 300 kHz currently permitted for MICS should apply across the entire MedRadio band to facilitate seamless use of the spectrum to meet the future needs of sophisticated implant devices that will transmit large quantities of patient data at high data rates.

In the NOI, the Commission requests information on a wide variety of topics, including the nature and function of future implant telemetry devices and the technical standards which these devices may require. BSCCRM notes that future medical implants are projected to have much different spectrum requirements than those in use today and urges the Commission, therefore, to exercise great care in fashioning regulations that are designed to accommodate future implant telemetry. For these reasons, BSCCRM urges the Commission to adopt the following changes in the MICS rules:

(1) Amendment of the MICS rules to expressly include inductive telemetry devices operating below 1 MHz;

(2) Expansion of the MICS allocation to include all of the 401-416 MHz band;

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[8] *In the Matter of Amendment of Parts 2 and 95 of the Commission's Rules to Establish The Medical Data Service at 401-402 and 405-406 MHz*, RM-11271, Comments of DexCom, Inc. (September 23, 2005).
[9] NPRM at ¶ 21

(3) Retention of 300 kHz maximum channel bandwidths and permission to aggregate of up to five channels in the band;

(4) Increasing permissible transmitter power levels by 16 dB for fixed frequency implants and 23 dB for spread spectrum implants and correction to the imbalance in permitted power levels that exists for uplink and downlink transmissions between implants and programmers; and

(5) Adoption of alternative methods of interference avoidance, such as the use of spread spectrum, along with raising the frequency scan sensitivity limits for implants that use listen-before-talk ("LBT") technology.

Discussion

I. Future of Implantable Medical Devices

The use of wireless telemetry in implanted devices will increase dramatically over the next ten years due to a large, aging population and the demand for increasingly sophisticated medical applications. There are on-going efforts to enable remote monitoring by incorporating RF telemetry into implantable drug pumps, artificial limbs, neuro-stimulators, implantable diagnostic devices, cochlear implants, and devices to electrically stimulate certain body activities, such as bladder function. These developments, combined with advances in the industry over the past 20 years, form the basis for the changes which BSCCRM proposes in these comments. Bandwidth needs for implant telemetry, for example, have grown exponentially over the past 20 years, and telemetry data rates have increased from 0.1 kbps in 1985 to nearly 100 kbps by 2005. BSCCRM believes that implant bandwidth needs will continue to grow, projecting data rates of 500 kbps over the next few years and approximately 5 mbps by 2015.

Memory in implanted devices has increased rapidly as well, from 0.1 kilobyte RAM in 1985 to approximately 1 megabyte RAM in 2005. BSCCRM expects device memory to continue to expand with the next generation of ICD implants featuring advanced diagnostics and high-speed bi-directional communications. New designs will store and download much larger quantities of heart rhythm based on new diagnostic functions that will greatly improve patient care. Current high end devices, for instance, can store up to 20 minutes worth of electrocardiograph data. In certain patients, this represents but a small fraction of the information that the physician would like to access. Having the ability to collect larger quantities of patient heart data will allow doctors to develop an overall picture of a disease's progression, instead of merely capturing a snapshot of an arrhythmia event, a limitation of current devices. In addition, devices with a greater capacity for data storage and transmission will improve the opportunities for earlier detection and more accurate and precise diagnosis of heart disease.[10]

Telemetry range has also experienced growth in the past 20 years, increasing from a couple of inches in 1985 to nearly 10 meters in 2005. To satisfy the growing demands for remote monitoring applications, discussed further below, doctors and patients will be demanding telemetry devices with the range of tens of meters. Furthermore, as remote monitoring, programming, and intervention become widespread, spectrum availability will become an issue. Unless the current spectrum allocation is significantly expanded, these demands will overwhelm the current allocation, slowing the deployment of new implant technologies and negatively impacting patient health care. In the end, manufacturers will be forced to abandon the MICS band for other, less congested portions of the spectrum, and the Commission's goal of creating a service for low power implantable medical devices will have been frustrated.

II. MICS Should Be Amended to Include Inductive Telemetry Devices Operating Below 1 MHz

BSCCRM is pleased that the Commission is proposing use of the 90-110 kHz band under MICS (or MedRadio), enabling medical implant telemetry to be regulated under the "license by rule" concept of Part 95.[11] As BSCCRM explained in its Petition

[10] For example, with increased bandwidth capable of supporting the transmission of these desired quantities of data, BSCCRM believes it can deploy devices that will capture and store several minutes of rhythm data, allowing the tracking of persistent arrhythmia patterns.

[11] BSCCRM notes the proposed legislation in H.R. 5441, the Coast Guard authorization bill, to eliminate the Loran-C program. This development underscores the diminishing use of Loran-C as a restricted band in need of protection from lower power telemetry applications like implantable medical devices.

for Rulemaking,[12] radiated emissions from inductive implants are so far below the ambient noise floor that they cannot be received more than six inches away from a patient's chest. Yet, because by-product radiated emissions from some inductive implants fall within the 90-110 kHz restricted band, unlicensed operation under Part 15 raises theoretical questions of compliance with the Commission's rules.[13] BSCCRM submits that a sound regulatory solution is to amend the MICS rules to include all inductive implants, operating below 1 MHz, on a licensed-by-rule basis, although these would not be subject to the traditional MICS technical regulations because of their very low power levels.[14] BSCCRM believes this proposal would be unopposed due to the very remote possibility of any interference from, or to, implants operating at these low inductive power levels.

III. The MICS Allocation Should be Increased by 12 MHz

By initiating this rulemaking, it is clear that the Commission recognizes that the public interest requires much-needed reform to the MICS band. It would be useful to have an internationally harmonized band that can accommodate all implantable devices, not merely the short range devices presently possible under MICS.[15] But by almost any measure, MICS has been an underutilized communications service due to the restrictive nature of the current rules. In the six years since the MICS service was established, only a handful of devices have been brought to the market most of which require a waiver to operate. A principal reason for the lack of development is the inadequate amount of

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[12] *In the Matter of Petition to Amend the Medical Implant Communications Service (MICS) Rules to Add Inductive Telemetry at 90-110 kHz, Expand the MICS Spectrum and Make Other Technical Changes in MICS*, Guidant Corporation Petition for Rulemaking (March 20, 2006), at 5 (hereinafter "BSCCRM Petition").

[13] Manufacturers have been forced to move to the 90-110 kHz band due to the demand for higher data rates for implants. Moreover, because inductive signals are wideband in nature, the 90-110 kHz band can not easily be avoided as implants "move up" in the spectrum. In addition, as BSCCRM pointed out in its Petition, manufacturers were not aware that the restricted band even applied to inductive devices. *See* BSCCRM Petition at 3-5.

[14] For inductive standards, Part 15 requirements can be retained for such devices.

[15] Because of present MICS restrictions BSCCRM has targeted the 902-928 MHz band for future development. But, as the Commission is aware, this band is heavily used. The staff of the Office of Engineering and Technology, concerned about crowding in the 902-928 MHz band, recommended that BSCCRM carefully consider operations in the MICS band. BSCCRM has concluded that in order for the MICS band to accommodate the future wave of implantable devices, considerable changes will have to be made.

spectrum allocated to MICS. Without a significant expansion of the MICS spectrum and needed changes to its operating rules discussed in later sections, MICS will continue to lie fallow.

Expanded memory, as BSCCRM is developing in its new devices, is an example of an advance that will drive the need for additional spectrum. For instance, as the amount of heart rhythm data collected and stored in an implant increases, the longer it will take to upload this information, in the same amount of spectrum, to the doctor or programmer for analysis. Increased spectrum and channel bandwidths, however, will speed up this process, shortening diagnostic and therapy sessions, minimizing the inconvenience to patients and lowering the cost of health care. Additionally, increased spectrum will permit the handling of multiple independent sessions among co-located patients without interference.

To meet the needs of future implant patients, BSCCRM estimates that the MICS allocation must be increased by a minimum of 12 MHz. An inspection of the spectrum allocations between 401-416 MHz reveals similar licensee profiles – primarily in the Meteorological Aids and satellite communications services – which suggests that the primary users of these bands will be able to accommodate a secondary allocation for MICS just as users in the "core" 402-405 MHz allocation do now.[16] Moreover, because MICS transmissions are designed to be of short duration, occur indoors and typically employ interference avoidance techniques of some kind, the primary users in these bands are assured of being unaffected by a secondary implant allocation. The expansion of MICS to the 401-416 MHz range will serve the public interest and, therefore, should be adopted by the Commission.

While BSCCRM does not in principle oppose accommodating body-worn devices in the current MICS band, it is concerned that encouraging expanded operations while increasing the allocation by only 2 MHz would compromise efficient use of the spectrum in patient-congested areas such as nursing homes or hospitals. Interference and spectrum overcrowding are also concerns in high risk locations such as operating theaters which require rapid transmission of patient data to monitoring equipment beyond the sterile field and out of the way of surgical teams. Non-implant telemetry devices, on the other

[16] *See* 47 C.F.R. § 2.106.

hand, typically feature high duty cycles and co-exist in the same geographic locations as low power medical implants. A common example of such a circumstance is the attachment of a host of devices to multiple patients in hospital wards to monitor their vital signs—e.g., blood pressure monitors, temperature monitors and pulse oximeters, which measure blood oxygen levels. The purpose of these devices requires them to be in constant communication with central monitoring terminals. Allowing non-implant telemetry devices in the MICS band without significant additional spectrum will limit the expansion of MICS applications and possibly require implant manufacturers to investigate other, less congested portions of the spectrum.

BSCCRM believes that other telemetry technologies such as Bluetooth, 802.11x, Zigbee and ultra wideband seem equally suited – and readily available – to transmit short-range medical data from body-worn monitoring devices like those being developed by Medtronic and others. BSCCRM suggests that, before the Commission adopts modifications to the MICS regulations that might adversely impact future implantable uses of the band, the Commission consider the viability of existing technologies as alternatives for devices that would otherwise be accommodated in, or near, the MICS allocations.

Finally, it is important to note that the additional spectrum requested by BSCCRM will make possible the use of frequency hopping spread spectrum techniques and thus, permit implants to be operated at higher power and transmit over greater distances. As explained in Section VI below, the coupling of spread spectrum technology with implants represents a workable alternative to the present LBT interference mitigation requirements in the MICS rules.

IV. Maximum Channel Bandwidth Should Be Maintained At 300 kHz

As noted in Sections I and III, the emerging generation of medical implant devices will require more, not fewer, communications channels. Demand for additional channels will be driven by the following factors: (1) exponentially increasing device memory required to store and transmit more data for improved patient care; (2) use of new patient sensors and increased monitoring of existing sensors; (3) more diagnostic uses for implantable medical devices generally; and (4) introduction of new implantable medical therapies. Thus, the Medtronic proposal to limit the use of implants in the proposed Wing Bands to 100 kHz channels runs counter to all of the trends in implant technologies. Unlike body-worn devices, which are readily accessible to the user and do not have a critical need to conserve battery power, implanted devices feature much different design constraints. To function over long periods without battery replacement, implants will need to transmit large quantities of data quickly, which cannot be done in 100 kHz channels.

Even the 300 kHz channel size allowed in the MICS band may be insufficient to maximize the longevity of future implants that store and transmit large amounts of data. Telemetry link speed and power consumption are becoming bottlenecks in the system. A low speed data link results in unacceptable delays in the transfer of time-critical implant data and an inconvenience to the physician and the patient. Long transfer times also result in higher power consumption by the telemetry device because it needs to be powered up for longer periods of time.

In order to permit the most flexible and efficient use of a new generation of medical implants, BSCCRM proposes that conventional fixed frequency implants be permitted to transmit in 300 kHz channels as is presently the case and, where necessary, be allowed to aggregate up to five adjacent 300 kHz channels for wideband telemetry. With many telemetry implants currently exceeding 100 kbps and data rates expected to increase to 500 kbps and higher over the next few years, wideband operations at 1500 kHz will not be that unusual in the next decade. Even should the Commission allocate less than the 15 MHz of spectrum BSCCRM requests, it should permit aggregating channels to facilitate the development of implants that will require such wideband operations.

V. The Power Permitted in the MICS Should Be Increased

There is a growing need for implants to communicate over greater distances than allowed by the current power levels of 25 microwatts EIRP (-16 dBm).[17] It is

[17] 47 C.F.R. § 95.639(f)(1). In a review of the proceeding establishing the MICS band, this limit appears to have been based only on Medtronic's reference to an International Telecommunication Union recommendation that sharing between the MICS and Metaids systems in the 401-406 MHz band is feasible if the EIRP of MICS transmitters is limited to 25 microwatts. *Report and Order*, in WT Docket

increasingly difficult, for example, to position implant monitoring equipment near patients to whom surgeons and other medical personnel require unfettered access during treatment. In operating theaters, in particular, implant monitoring equipment must be located outside the "sterile field." Yet, under the power limits permitted for MICS, patients are virtually "tethered" to monitoring equipment that can be located at most, 6 to 8 feet away, often not far enough from the operating table. Furthermore, where multiple patients reside in a common area (e.g., nursing homes or hospital wards), increasing the distance over which implanted devices can communicate makes independent device interrogation sessions with individual patients more economical and more convenient.

Moreover, as implant technologies evolve and become an integral component of health management, wireless remote patient monitoring 24 hours a day will become the standard of care. Such round-the-clock operations will require monitoring of patients in their homes and work environments with as little impact on mobility as possible. To serve multiple patients in congested environments, as well as to function beyond the sterile field of an operating theater, BSCCRM estimates that an increase in power to 0 dBm EIRP will be required for conventional fixed frequency MICS transmitters. For frequency hopping transmitters, which are much less prone to causing or receiving interference, BSCCRM urges the Commission to adopt peak power levels of +7 dBm EIRP. These increased power levels will enable transmissions at distances of up to 100 feet, which would generally be sufficient to monitor a patient in and around a residence or work environment. Permitting a significantly greater communication range will allow implant patients to conduct routine activities without being "tethered" to local monitoring equipment.

As a related matter, BSCCRM notes that under the existing rules there is an imbalance between the computation of power from implants and external devices. The rules allow measured emissions from an implant (i.e. the downlink) to take into account the loss caused by tissue absorption and antenna loss, but do not allow for such loss when measuring the uplink from an external device.[18] The resulting asymmetric communications link can vary by as much as 16 dB, a disparity that can reduce the

No. 99-66 (Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band), 14 FCC Rcd 21040 (1999), at ¶ 8.

potential operating range of the entire system. Accordingly, BSCCRM recommends that the Commission rectify the imbalance in transmission links that are inherent to the MICS rules by allowing 16 dB more power in the uplink direction.

VI. The Commission's Interference Avoidance Rules Should Be Revised

BSCCRM believes that the Commission's current frequency monitoring requirements in Section 95.628 stifle innovation in developing solutions for spectrum interference and are inadequate to address future needs and competing spectrum uses. In this regard, the frequency scan sensitivity levels (-96 dBm)[19] for MICS devices are far too low and add unnecessary costs to implant systems. BSCCRM believes that the detection limits for interference could be increased to -86 dBm peak without increasing the risk to other band users. BSCCRM urges the Commission, therefore, to adopt these higher detection limits for LBT technology.

More to the point, however, BSCCRM believes that the LBT requirement adversely impacts the use of the MICS band and should not be mandated. The implementation of LBT burdens devices with a complex and computation-intensive protocol that significantly increases both the receiver and protocol complexity that an implanted device must support to communicate with an external device. Receiver complexity increases due to the demands placed on device sensitivity to reliably detect interferers in the presence of dynamic fading. In addition, the increase in protocol complexity leads to excessive delays in the transfer of data and to increased times when the device must stay "awake" to support communications. Both of these factors adversely impact device longevity and increase the drain on implant battery power.

BSCCRM submits that the LBT technology should not be the only method of avoiding interference. The risk of interference can be greatly reduced, or eliminated, by implants that use frequency hopping spread spectrum techniques. This dynamic and proven interference avoidance technique offers distinct advantages over the fixed frequency monitoring requirements for MICS and complements BSCCRM's overall

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[18] 47 C.F.R. § 95.639(f)(1)-(2).
[19] *Id.* at § 95.628.

proposal for an increased spectrum allocation and improved power levels. Because any interference encountered from a spread spectrum implant would be transient (and non-harmful) there should be no frequency scan, or LBT, requirement for implants which feature dynamic spectrum monitoring techniques such as frequency hopping.

In summary, BSCCRM's position is that restricting the protocol in the band to one particular implementation reduces the choices available to manufacturers to successfully implement reliable communications links and thus works against the public interest. Mandating a particular protocol is also counter-productive to allowing technical advances and innovation to improve the telemetry links needed in the MICS band.

Conclusion

BSCCRM supports the efforts of the Commission to reform the MICS band. It is in favor of increasing the spectrum allocated to MICS, adopting a more flexible channelization policy, permitting an increase in power and permitting new methods of interference control. BSCCRM also respectfully urges the Commission to consider the revisions to the MICS operating rules proposed by BSCCRM to enable the efficient use of spectrum by new generations of sophisticated implant devices.

Respectfully submitted,

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